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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,221	FLEISCHMAN ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-20 and 34-61* is/are pending in the application.

4a) Of the above claim(s) *14-20,34-44 and 46-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45 and 50-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 45 and 50-61 in the reply filed on August 2, 2006 is acknowledged.

Claim Objections

2. Claim 55 is objected to because of the following informalities:

The preamble appears to be lacking a term such as "comprising" or "consisting". See for example claim 45, which includes the term "comprising." Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 45 and 50-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claims 45 and 55, the phrase "the fluid outlet at the collection area." There is insufficient antecedent basis for this limitation in the claim. Although the embodiments "fluid outlet" and "collection area" are recited in the independent claims, their physical relationship with each other is not defined prior to the phrase.

6. In claim 60, line 3, the phrase "for directed light towards said sensor portion" is vague and indefinite. It is unclear whether the term "directed" is an adjective that describes the light, or an active manipulation of the light (i.e. directing). Applicants are requested to clarify the instant claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 45 and 50-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Jain et al (US 2002/0081714 A1).

Jain et al teach a magnetic chip comprising a silicon substrate 25 (i.e. semi-conductor substrate) with magnetic islands 26 (i.e. at least one magnetic portion)

thereon in a pattern that produces gaps in between the islands (i.e. comprises two magnetic pole pieces having an interpolar gap) such that magnetic beads can be trapped within the gaps by localized magnetic fields from the islands (i.e. magnetically manipulate magnetically susceptible particles into collection area). See page 6, section 0056; page 7, sections 0076-0077; page 10, section 0092; page 11, section 0113; page 12, section 0123; and Figures 1C-D. Jain et al also teach a microfluidic assembly integrated with the chip and comprising a plurality of channels, sample inlet, and sample outlet ports (i.e. a fluid outlet), wherein the microfluidic assembly can be glass (i.e. transparent wall). See page 13, section 0136. Jain et al further teach on-chip photodetectors at the attachment sites of magnetic particles (i.e. at least one photosensitive sensor portion in physical communication with the fluid outlet; sensor portion being disposed within the interpolar gap) for detection of signals from beads, probes, and/or targets, wherein the detectors can be a photodiode, and wherein the signals can be fluorescence (i.e. light source that emits light of the predetermined wavelength to excite the one immunofluorescently labeled particles). See page 14, sections 0142-0143 and Figure 12.

In regards to claims 50-51, Jain et al teach spin valve sensors that detect local magnetic fields by measuring the resistance in a strip of material while current is passed through it. See page 20, section 0202.

In regards to claim 53, Jain et al teach sample outlet ports (i.e. plurality of flow outlets) as disclosed above, and that the chip can comprise a plurality of arrays comprising the magnetic islands, each array being addressed by two crossed channels

that can both introduce and remove reagents (i.e. provide an associated collection area within each of the plurality of flow outlets). See pages 13-14, sections 0133 and 0136-0137; and Figure 3.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (US 2002/0081714 A1) in view of Zborowski et al (Cytometry, 1996).

Jain et al reference has been disclosed above, but fails to teach that the plurality of flow outlets are arranged to run along mutually parallel paths and the at least one magnetic portion comprises two magnetic pole pieces, extended across the plurality of parallel paths as to magnetically manipulate magnetically susceptible particles within each of the plurality of flow outlets.

Zborowski et al teach a ferrograph with two pole pieces of a permanent magnet that simultaneously provides a magnetic barrier for a plurality of channels, in order to separate five difference cell samples simultaneously, which is significantly faster than using a single-channel design. See page 256, right column, 1st paragraph to page 257, left column, first paragraph; and Figure 1 and caption.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Jain et al by substituting the array format with a ferrograph having two pole pieces of a permanent magnet that simultaneously provides a magnetic barrier for a plurality of channels, as taught by Zborowski et al, in order to separate five different cell samples simultaneously, which is significantly faster than using a single-channel design. Because the two pole pieces of Zborowski et al are

separate from the fluidic channels, they allow for more efficient separation of single-cell samples using individual channels, thereby providing the motivation to combine Jain et al and Zborowski et al references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the two pole pieces of Zborowski et al as the only magnetic force on the microchip of Jain et al, since Jain et al teach a linear setup of multiple magnetic localizations, and the pole pieces and separate channels of Zborowski et al accommodate such a linear setup.

13. Claim 55-58 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (US 2002/0081714 A1) in view of Ellis et al (US 4,091,280).

Jain et al reference has been disclosed, but fails to teach that the bioferrograph includes a light source that emits light of the predetermined wavelength to excite the one immunofluorescently labeled particles.

Ellis et al teach the use of a single fiber optic cable for both the transmission and return of light signal, in order to reduce duplication and volume of material. See column 4, lines 5-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Jain et al with a single fiber optic cable having the capability of conveying both transmitted and return light signals, as taught by Ellis et al, in order to reduce duplication and volume of material. The advantage of using minimal material, especially for the small arrays taught by Jain et al, provides the motivation to combine the teachings of Jain et al and Ellis et al. In addition, one of ordinary skill in the

art at the time of the invention would have had a reasonable expectation of success in applying the single fiber optic cable of Ellis et al to the apparatus of Jain et al, since Jain et al teach photodiode detectors, and the fiber optic cable of Ellis et al is capable of attaching to photodiodes. See column 3, line 65.

In regards to claim 61, Jain et al teach data processing using image processing tools and software. See page 7, section 0076,

14. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (US 2002/0081714 A1) in view of Ellis et al (US 4,091,280) as applied to claim 55 above, and further in view of Zborowski et al (Cytometry, 1996).

Jain et al and Walt et al references have been disclosed above, but fail to teach that the plurality of flow outlets are arranged to run along mutually parallel paths and the at least one magnetic portion comprises two magnetic pole pieces, extended across the plurality of parallel paths as to magnetically manipulate magnetically susceptible particles within each of the plurality of flow outlets.

Zborowski et al teach a ferrograph with two pole pieces of a permanent magnet that simultaneously provides a magnetic barrier for a plurality of channels, in order to separate five difference cell samples simultaneously, which is significantly faster than using a single-channel design. See page 256, right column, 1st paragraph to page 257, left column, first paragraph; and Figure 1 and caption.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Jain et al and Walt et al by substituting the array

format with a ferrograph having two pole pieces of a permanent magnet that simultaneously provides a magnetic barrier for a plurality of channels, as taught by Zborowski et al, in order to separate five different cell samples simultaneously, which is significantly faster than using a single-channel design. Because the two pole pieces of Zborowski et al are separate from the fluidic channels, they allow for more efficient separation of single-cell samples using individual channels, thereby providing the motivation to combine Zborowski et al with Jain et al and Walt et al references. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in including the two pole pieces of Zborowski et al as the only magnetic force on the microchip of Jain et al and Walt et al, since Jain et al and Walt et al teach a linear setup of multiple magnetic localizations, and the pole pieces and separate channels of Zborowski et al accommodate such a linear setup.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 45, 50-52 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 7, and 15-21 of U.S. Patent No. 6,623,984. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims contain all the embodiments of the instant claims. For example, the patent claims teach a substrate comprising silicon (i.e. semi-conductor substrate), the substrate comprising a flow channel with an inlet and outlet portion (i.e. comprising a fluid outlet), a magnetic structure in physical communication with the topside and backside portions of the substrate (i.e. magnetic portion in physical communication with semi-conductor substrate), and a bioferrograph comprising a sensor portion (i.e. sensor portion in physical communication with the fluid outlet at a collection area). See especially claims 2, 7, and 15.

Conclusion

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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